

**REMARKS**

Claims 84, 97 and 102 are supported by the specification, page 3, lines 22-29; from page 15, line 24 to page 16, line 7 and page 28, lines 9-11. Claim 98 is supported by claim 97. Claims 104-106 are supported by claims 84, 97 and 102. Claims 107, 110 and 112 are supported by claim 88. Claims 108 and 109 are supported by claims 89 and 90, respectively. Claim 111 is supported by claim 86.

No new matter has been added. Claims 84-90 and 97-112 are present and active in the application.

Creutzfeldt-Jakob Disease (CJD) is a relatively rare form of human neurodegenerative disorder. The emergence of a new variant form (vCJD) of the disease, possibly due to consumption of bovine spongiform encephalopathy (BSE)-infected meat products, has raised the possibility of a large increase in the number of cases. A significant risk, from all forms of CJD, via other transmission routes includes surgery, transplants, transfusion or contaminated medical products. Transmissible spongiform encephalopathy (TSE) agents, which are responsible for all forms of CJD in humans are highly resistant to inactivation. A variety of treatments for inactivating TSE agents are currently in development. However, the uniquely stable properties of the TSE agents indicate that a validation procedure is required to provide a relevant indication of the performance of processes to inactivate such agents.

The present invention discloses measuring the activity of a thermostable kinase before and after a treatment process. The reduction in activity of the thermostable kinase by the treatment can be correlated with the reduction in amount or activity of the biological agent, subjected to the same treatment process, to determine whether the amount or activity of the biological agent has been reduced below an acceptable level. When a level of activity that correlates with an acceptable reduction in the biological agent is reached, the treatment is regarded as validated.

**Rejections under 35 U.S.C. § 112**

The rejection of claims 84-90, under 35 U.S.C. § 112, second paragraph, as being incomplete, has been obviated by appropriate amendment. Claim 84 has been amended to recite additional steps (ii) and (iii). As amended, claim 84 describes the

validation of a treatment process for reducing the amount of activity of a contaminating biological agent in a sample. Withdrawal of this ground of rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 103**

The rejections of claims 84-90 and 97-103 under 35 U.S.C. 103(a) over the combined teachings of U.S. Patent 6,913,896 (Raven et al.), WO 02/053723 (Raven) and Kath et al., are respectfully traversed. None of the cited references describes measuring the activity of a thermostable kinase before and after a treatment process.

Raven et al. discloses an assay to detect an analyte in a sample (column 3, lines 42 to 44). In Raven et al., a thermostable kinase is coupled to a binding agent, for example, an antibody, specific for an analyte, and acts as an amplifier of the reaction between the analyte and the antibody (column 3, lines 5 to 9). The use of the “detector kinase” enables rapid and sensitive detection and quantification of the analyte (column 10, line 66 to column 11, lines 1 to 14). However, Raven et al. does not describe measuring the activity of a thermostable kinase before and after a treatment process. Furthermore, Raven et al. does not describe validating a treatment process.

Raven describes a process for inactivating a TSE agent, comprising exposing the TSE agent to a thermostable proteolytic enzyme (page 4, lines 21 to 22). Raven separately describes antibody-based methods for detecting infective material, which can be performed either prior to, or after carrying out, a sterilization process (page 8, lines 18 to 21). However, Raven does not describe measuring the activity of a thermostable kinase before and after a treatment process.

Kath et al. merely describe the identification and characterization of the *S. acidocaldarius* adenylate kinase gene (Kath et al., Abstract). Kath et al. report the cloning, sequencing and expression in *E. coli* of a new thermostable adenylate kinase (Id.). However, Kath et al. do not describe measuring the activity of a thermostable kinase before and after a treatment process.

The claims are direct to a method of validating a treatment process including measuring the activity of a thermostable kinase before and after a treatment process. The cited references fail to disclose measuring the activity of a thermostable kinase


before and after a treatment process. Raven *et al.*, which discloses a method to detect an analyte in a sample, does not suggest to a person skilled in the art measuring the activity of a thermostable kinase before and after a treatment process. Raven, which discloses a process for inactivating a TSE agent, in which the agent is exposed to a thermostable proteolytic enzyme, does not suggest to a person skilled in the art measuring the activity of a thermostable kinase before and after a treatment process. Kath *et al.*, which report the molecular cloning and characterization of a new thermostable kinase, do not suggest to a person skilled in the art measuring the activity of a thermostable kinase before and after a treatment process. The applied references fail to suggest measuring the activity of a thermostable kinase before and after a treatment process. Accordingly, Applicants submit that the claimed invention is not obvious over the cited references. Withdrawal of this ground of rejection is respectfully requested.

#### **Provisional Obviousness-Type Double Patenting Rejection**

The provisional obviousness-type double patenting rejection of claims 84-90 and 97-103 over claims 1-12, 16-21 and 23-35 of Application No. 12/918,628 is respectfully requested to be held in abeyance, until the indication of allowable subject matter in this application or Application No. 12/918,628. Upon the indication of allowable subject matter the provisional rejection should be withdrawn, and the provisional rejection in the other application made non-provisional. Such action is respectfully requested.

Applicants submit that the application is now in condition for allowance. Early notice of such action is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul E. Rauch', is written over a horizontal line. The signature is stylized with loops and a long horizontal stroke extending to the right.

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